K123311

JAN 14 2013

510(k) Summary

Date Prepared: October 5, 2012

510(k) Submitter	Contact Person
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General Information	
Trade Name	Access & Support Catheter
Common Name	Support catheter
Classification Info	Percutaneous catheter per 21 CFR 870.1250 (Class II); Product Code: DQY
Predicate Device	Minnie Support Catheter – Vascular Solutions, Inc. (K082337) Quick-Cross Support Catheter – Spectranetics, Inc. (K033678)

Device Description

The Access & Support Catheter is an over-the-wire (OTW) single-lumen catheter with an atraumatic tapered tip. The catheter is offered in twelve (12) size models as outlined in the following table.

Model #	Guidewire Compatibility	Shaft Outer Diameter (proximal / distal)	Working (Effective) Length	Markerband Quantity	Markerband Spacing
9002-001	0.014"	0.039"/0.0265"	65cm	3	15 mm
9002-002	0.014"	0.039"/0.0265"	90cm	3	15 mm
9002-003	0.014"	0.039"/0.0265"	135cm	3	15 mm
9002-004	0.014"	0.039"/0.0265"	150cm	3	15 mm
9002-005	0.018"	0.044"/0.0305"	65cm	3	15 mm
9002-006	0.018"	0.044"/0.0305"	90cm	3	15 mm
9002-007	0.018"	0.044"/0.0305"	135cm	3	15 mm
9002-008	0.018"	0.044"/0.0305"	150cm	3	15 mm
9002-009	0.035"	0.063"/0.0505"	65cm	3	50 mm
9002-010	0.035"	0.063"/0.0505"	90cm	3	50 mm
9002-011	0.035"	0.063"/0.0505"	135cm	3	50 mm
9002-012	0.035"	0.063"/0.0505"	150cm	3	50 mm

The catheter shaft consists of high density polyethylene (HDPE) with distal platinum/iridium markerbands. The distal 40 cm outer portion of all catheters have a hydrophilic coating. The proximal portion includes a PEBA strain relief with a HDPE manifold which incorporates a female luer connection which communicates with the catheter lumen. The catheter through lumen is used to pass the catheter over the appropriate guidewire or for infusion. When used for

infusion, the maximum infusion pressure should not exceed 300 psi. The catheter guidewire compatibility size and length are printed on the strain relief. All models are compatible with 5 Fr introducer sheaths and 6 Fr guiding catheters. All devices are provided sterile and intended for single use only.

Intended Use / Indications
The Access & Support Catheter is intended for use during coronary and peripheral interventional procedures to guide and support guidewires, traverse discrete portions of the vasculature, allow for guidewire exchanges and provide a conduit for infusion of saline solution, diagnostic contrast agents and therapeutic agents.

Comparison to Predicates
The indication for use of the Access & Support Catheter is comparable to the predicate devices with the differences being mainly semantics. Both devices are intended to support access to the vasculature, allow for guidewire exchanges, and provide a conduit for fluid deliveries. The Access & Support Catheter uses the terms "discreet portions of the vasculature" as a more descriptive term compared to the Quick-Cross general "access of the vasculature." For comparison, the Minnie Support Catheter also uses the "discreet regions" terms as further description of the type of vasculature the catheter can be used within.

The Access & Support Catheter is technologically similar to the predicate devices in that they all are single lumen catheters utilized to exchange guidewires and/or infuse intravascular procedural agents as necessary. The Minnie Catheter is constructed of similar materials (polyethylene and hydrophilic coating) with similar working lengths ranging in size from 65cm to 150cm, and the same dimensional guidewire compatibility (0.014", 0.018", and 0.035"). The Quick-Cross Support Catheter is constructed of similar materials (HDPE, Pt/Ir, and hydrophilic coating) and ranges in length from 90cm to 135cm with the same guidewire compatibilities. The following table outlines a comparison of the subject device to the predicate devices.

Device Component / Performance Parameter	QXMédical Access & Support Catheter	Quick-Cross Catheter (K033678)	Minnie Catheter (K082337)
Manifold/Proximal Hub	HDPE	Same	PE
Strain Relief	PEBA	Molded from hub (HDPE)	unknown
Catheter Shaft	Single lumen, HDPE	Same	Single lumen, PE
Coating	Hydrophilic	Same	Same
Markers – Material (Quantity)	Pt/Ir (3)	Same	Material unknown (3)
Infusion Pressure	300 psi	Same	Same
Outer Diameter	Varies by model Proximal: 0.039", 0.044", 0.063" Distal: 0.0265", 0.0305", 0.0505" Tip: 0.0195", 0.0225", 0.0405"	Varies by model Proximal: 0.039", 0.044", 0.063" Distal: 0.0260, 0.030, 0.050" Tip: 0.020, 0.023, 0.041"	Varies by model Proximal: 0.039, 0.044, 0.063" Distal: 0.026, 0.030, 0.050" Tip: 0.020, 0.023, 0.041"
Effective (Working) Length	All three diameters 65, 90, 135, 150 cm	Varies by model 90, 135, 150 cm	Varies by model 65, 90, 135, 150 cm
Guidewire Diameter (min.)	0.014", 0.018", 0.035"	Same	Same
Guide Catheter (max.)	5Fr	Same	5Fr or 6Fr
Access Sheath (max.)	5Fr	Same	Same
Single Use, Sterile	Yes	Same	Same
Sterilization Method	EO	Unknown	Same

Summary of Non-Clinical Performance Data

The Access & Support Catheter has been evaluated using the following *in vitro* bench testing to confirm the performance characteristics of the device.

- Visual inspections
- Dimensional evaluations
- Luer syringe compatibility
- Guidewire compatibility
- Sheath compatibility
- Guidewire support
- Catheter stiffness & flexibility, guidewire retraction & re-insertion
- Catheter fatigue
- Catheter kink resistance
- Markerband retention
- Leakage/burst (Pressure & Vacuum)
- Torque testing
- Tensile testing
- Corrosion testing
- Simulated Use
- Coating Adherence
- Particulate Evaluations
- Shelf life
- Package Integrity

Biocompatibility tests were completed to ensure all materials utilized to construct the Access & Support Catheter were biocompatible. Biocompatibility tests included:

- Cytotoxicity
- Sensitization
- Irritation / Intracutaneous Reactivity
- Systemic Toxicity (Acute)
- Genotoxicity
- Hemolysis
- Immunology (Compliment Activation)
- *In Vivo* Thromboresistance
- Pyrogenicity (material mediated)
- Physicochemical Tests

All tests demonstrated the materials, manufacturing processes, and design of the Access & Support Catheter met the established performance criteria and will perform as intended. The above non-clinical tests demonstrate that the device is safe and effective and performs as safely and effectively as the legally marketed predicate devices.

Substantial Equivalence Comparison Summary

Based upon the intended use and descriptive information provided in this pre-market notification, the QXMédical Access & Support Catheter has been shown to be substantially equivalent to the predicate devices. The QXMédical Access & Support Catheter raises no new questions of safety or effectiveness when compared to the predicate devices and is, therefore, substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

QXMedical, LLC
c/o Mark Job
Regulatory Technology Services, LLC
1394 24th Street NW
Buffalo, MN 55313

JAN 14 2013

Re: K123311
Trade/Device Name: VELO Access and Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: November 20, 2012
Received: November 21, 2012

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123311

Device Name: **QXMédical Access & Support Catheter**

Indications for Use:

The Access & Support Catheter is intended for use during coronary and peripheral interventional procedures to guide and support guidewires, traverse discrete portions of the vasculature, allow for guidewire exchanges and provide a conduit for infusion of saline solution, diagnostic contrast agents and therapeutic agents.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M A Hillebrenner